

AE pharmaceutical composition comprises a nucleic acid or a cell comprising a nucleic acid, the expression of which is desired in said gastrointestinal or genitourinary cells; whereby said method induces an immune response in said recipient specific to the gene product encoded by said nucleic acid.

Claim 13, line 2: please delete "non-toxic".

AE Claim 26 (amended):

26. A suppository comprising a biologically active nucleic acid, wherein said suppository induces in an immune response in a recipient thereof.

#### Remarks

Claims 1-28 are currently pending in the subject application. Claim 1 has been amended to correct an antecedent basis problem by including the term "genitourinary" in the preamble. Claim 1 has also been amended to recite that the claimed method induces an immune response in the recipient. Furthermore, claim 26 recites that the suppository induces an immune response. Support for these amendments is found throughout the specification, and, in particular, the Summary and Example 12. For further clarification purposes, claim 13 has been amended by deleting the term "non-toxic." Upon entry of this Amendment, claims 1-28 will be before the Examiner for consideration.

Claims 1-19, 27, and 28 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that is not enabled by the specification. Applicants traverse in part, and otherwise assert that the amendments to the claims above obviate this rejection. The outstanding office action cites numerous references to outline the current state of the art in the fields of physiology and gene therapy. Applicants generally agree with the Examiner's position that these arts can be unpredictable. However, Applicants first assert that the Patent Office's position on the state of the art, and the references in support thereof, focus on gene therapy and much less, if at all, on vaccines and vaccination. The